

REMARKS

Claim 1 is amended, claims 11-14 are canceled and claim 24 is added herein. Claims 1-10 and 15-24 will be pending upon entry of the amendment.

The following remarks are responsive to the Office action dated August 5, 2005.

The specification is amended herein to update the current status of the parent application in accordance with the Office's requirement.

Claim 1

Claim 1 as amended herein is directed to a chlorine dioxide gas generating kit, wherein the kit comprises:

- a chlorine dioxide gas generating apparatus comprising:
- a container having a flexible outer wall defining an interior chamber of the container;
- a first reaction component and a second reaction component disposed within the interior chamber of the container; and
- at least one rupturable membrane disposed within the interior chamber of the container and separating the first and second reaction components, the at least one rupturable membrane being constructed of glass, whereby upon rupture of the rupturable membrane the first and second reaction components contact each other to thereby form a reaction in which chlorine dioxide gas is produced within the container;

the container being adapted for exhausting the chlorine dioxide gas therefrom; and

a substantially rigid receptacle defining an internal cavity sized and shaped for receiving at least a portion of the container of the chlorine dioxide gas generating apparatus so as to inhibit flexing and bending of the container to thereby

inhibit unintended rupturing of said at least one rupturable membrane of the apparatus, the apparatus being removable from the receptacle for activating the apparatus to generate chlorine dioxide gas.

Constructing the rupturable membrane from glass, e.g., instead of a film pouch or plastic that must be squeezed to rupture the pouch as in the cited art, increases the number of rupturing stimuli that can be used. For example, in addition to squeezing, the glass membrane may be ruptured by bending, by ultrasonic stimuli, by thermal stimuli and/or by electromagnetic stimuli.

Claim 1 as amended herein is submitted to be non-obvious in view of and patentable over the references of record, and in particular any one of U.S. Patent Nos. 4,998,671 (Leifheit), 5,126,070 (Leifheit et al.) and 6,602,466 (Hamilton et al.), in combination with U.S. Patent No. 6,189,688 (Aeneas), in that whether considered alone or in combination the references fail to disclose or suggest chlorine dioxide gas generating kit that includes apparatus having first and second reaction components are separated by a rupturable membrane constructed of glass whereby rupturing of the glass membrane results in contact between the reaction components to form a reaction in which chlorine dioxide gas is produced.

Leifheit is directed to a multiple compartment flexible package including a container (10) comprising an upper receiving compartment and a lower dispensing compartment (12). One or more rupturable containers or pouches (20) are disposed within the receiving compartment and may contain components that when mixed together produce chlorine dioxide gas. However, Leifheit clearly fail to disclose or even suggest that the pouches (20) are constructed of glass.

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Leifheit et al. is directed to a chlorine dioxide generator comprising (with reference to Fig. 3) a rupturable interior pouch (220) containing a reactant and covered by an absorbent material substrate (230) containing particulate reactant. The pouch/substrate combination is enclosed within a compartment (25) defined by opposing liquid impermeable substrates (255, 265). The pouch (220) is disclosed by Leifheit et al. as being constructed of two film layers sealed together at their peripheral edges. See column 3, lines 6-19. Thus, Leifheit et al. also fail to disclose or even suggest a rupturable membrane constructed of glass.

Hamilton et al. disclose apparatus and methods for controlled delivery of a gas, including chlorine dioxide gas. In one embodiment (Figs. 12A, 12B and 12C), the apparatus disclosed by Hamilton et al. comprises an envelope layer (520), a sachet layer (530) adjacent the envelope layer, a barrier layer (550) adjacent the sachet layer (520), and reactant (540) disposed in the volume defined by the sachet layer (530) and the barrier layer (550). Hamilton et al. disclose that the barrier layer (550) may be constructed of glass (column 24, lines 36-38). This is the only embodiment disclosed by Hamilton et al. in which a component of the apparatus may be constructed of glass.

However, Hamilton et al. clearly fail to disclose 1) first and second reaction components separated by a rupturable membrane, and 2) a rupturable membrane constructed of glass. Specifically, the apparatus disclosed in Figs. 12A-C of Hamilton et al. is not activated by rupturing a component of the apparatus. Rather, the apparatus contains only a single reactant mixture (column 23, line 5-8) that can generate chlorine dioxide gas in the presence of an initiating agent

such as water. Thus, the water is not present within the apparatus. Rather, to activate the apparatus it is placed in water and water diffuses through the envelope layer and sachet layer to mix with the reactant.

For this reason, there is no rupturable component to the apparatus disclosed in Figs. 12A-C of Hamilton et al. Specifically, there is clearly no disclosure that the barrier layer (250) is ruptured to allow contact between the reactant and the initializing agent. Rather, the initiating agent contacts the reactant upon diffusing through the envelope layer and sachet layer (column 23, lines 17-30 and lines 49-60).

In fact, the only embodiment disclosed by Hamilton et al. in which a component of the apparatus is ruptured to activate the apparatus is the embodiment shown in Figs. 3A and 3B. In that embodiment, the initializing agent is contained within a frangible pouch (260) constructed of a multi-layer plastic e.g., polyolefin, envelope having a weak layer positioned near the sealing surface that will fail under pressure (column 20, lines 1-4). Thus, Hamilton et al. fail to disclose or suggest any embodiment having a component that ruptures to allow contact between reactants and wherein the rupturable component is constructed of glass.

Aneas discloses a multi-chamber dispensing container for storing at least two substances and the extemporaneous mixture of these substances. In particular, the substances are disposed in a tubular container constructed of an elastically deformable material (e.g., low-density polyethylene or polypropylene). See column 3, lines 31-36. An occlusion means (7) within the container separates the two substances therein. The occlusion means (7) is disposed obliquely within the container and is tearable away from the container side wall

under the effect of transverse activating pressure of the user's fingers against the sides of the container side wall.

According to Aneas, the occlusion means (7) is preferably, but not obligatorily, constructed of the same maerial as the container. No materials other than elastically deformable materials are disclosed by Aneas as being suitable for construction of the occlusion means (7). Accordingly, Aneas fails to disclose or even suggest a ruputurable membrane constructed of glass.

Because Leifheit, Leifheit et al., Hamilton et al. and Aneas et al. each fail to disclose or suggest a rupturable membrane constructed of glass, a combination of these references likewise fails to disclose or suggest such a feature. For these reasons, claim 1 as amended is submitted to non-obvious in view of and patentable over these references.

With respect to the other references of record, it is noted that U.S. Patent Nos. 4,528,268 (Andersen et al.) and 5,073,488 (Matner et al.) are each directed to apparatus for testing the sufficiency of sterilization. In general, the references disclose a container (e.g., container 2 of Andersen et al. and container 10 of Matner et al.) comprising a rupturable glass ampoule (designated 4 and 18, respectively, in these references) and bacteria or a bacterial enzyme substrate (designated 14 and 16, respectively, in these references) disposed inside the container. The glass ampoule houses a liquid growth medium for bacteria or the like. The container must be bacteria impermeable to protect against contamination of the container. In use, the container is placed in a sterilization unit along with objects to be sterilized. After sterilization and removal from the sterilization unit, the glass ampoule is ruptured inside the container, therein

releasing the growth medium so that the medium and bacteria are in contact within the apparatus.

The container is then incubated at a temperature that fosters bacterial growth. The amount or effectiveness of the sterilization unit is determined by bacteria growth within the apparatus, i.e. if bacteria grow, especially in large quantities, then the sterilization was not effective. In a conventional apparatus, after sterilization the bacteria substrate would be removed from a container and transferred to a culture dish of medium, leading to contamination by both the culture dish and transference. Therefore, the purpose of the apparatus is to keep out bacteria and microorganisms that may contaminate the medium or substrate.

Obviousness can only be established by modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references or in the knowledge generally available to one of ordinary skill in the art. MPEP § 2143.01 citing In re Kotzab, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). The mere fact that a prior art reference may be modified to obtain the claimed invention does not make the claimed invention obvious if there is no suggestion or motivation in the reference to make the modification. In re Mills, 916 F.2d 680, 682, 16 U.S.P.Q.2d 1430, 1432 (Fed. Cir. 1990). Applicants submit that there is no teaching, suggestion or motivation found in the references of record as to why one would replace the polymeric membranes of the apparatus disclosed by Leifheit, Leifheit et al. and Hamilton et al. with the glass membranes of Andersen et al. and Matner et al., nor is there any teaching by any of the references of the

desirability of rupturable glass membranes to permit rupturing by non-compressive stimuli.

The apparatus recited in claim 1 provides a rupturable membrane constructed of glass so that, when desired, the membrane can be ruptured from a position remote from the apparatus, such as by ultrasonic stimuli or other noncompression type stimuli, to activate the apparatus. This allows the user to be remote from the chlorine dioxide gas produced following activation of the apparatus.

The stimuli used to rupture the polymeric membranes used in the chlorine dioxide generating apparatus of Leifheit, Leifheit et al. and Hamilton et al. are limited to compression, thereby requiring the user to apply the needed compression. Neither of these references discloses or otherwise even suggests any advantages associated with using a rupturable glass membrane instead of a polymeric film membrane. The glass ampoules of the apparatus disclosed in Andersen et al. and Matner et al. are used to maintain a sterile environment. There is no suggestion, or recognition, by Andersen et al. and Matner et al. of the need for using a rupturable glass membrane to allow stimuli other than compressive stimuli to activate the apparatus. Indeed, those references disclose compression as the sole means for breaking the glass ampoules. Thus, one skilled in the art would not be motivated by Andersen et al. nor Matner et al. to replace the polymeric membranes of the gas generating apparatus of Leifheit, Leifheit et al. and Hamilton et al. with a glass membrane.

Moreover, a combination of prior art references that makes a prior reference unsatisfactory for its intended purpose may be considered to teach away from the proposed combination, thereby supporting a showing of non-obviousness. See MPEP

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2143.01 citing <u>In re Gordon</u>, 733 F.2d 900, 902 (Fed. Cir. 1984). Replacing the polymeric membranes of Leifheit, Leifheit et al. and Hamilton et al. with a rupturable glass membrane would have unsatisfactory results That is, the outer casing of each of the apparatus of Leifheit, Leifheit et al., and Hamilton et al. is made from material that inherently may be punctured and/or torn if glass is ruptured inside the apparatus. Leifheit discloses the outer pouch being made from a pliable polymeric film (column 6, lines 12-13). Leifheit et al. disclose the substrates 30 and 130 being made from meltblown polypropylene fabrics or dry carded thermally bonded blends of rayon and polypropylene (column 5, lines 24-27) and substrates 230 and 255 being made from film material such as spun-bonded polypropylene nonwoven (column 5, lines 45-48). Hamilton et al. disclose an envelope 20 constructed of a film or membrane. Rupturing of a glass membrane within each of these constructions would rupture the construction, thereby rendering the apparatus unsuitable for its intended purpose.

For these additional reasons, claim 1 as amended herein is submitted to be non-obvious and patentable over the references of record.

Claims 2-10 depend directly or indirectly from claim 1 and are submitted to be patentable over the references of record for the same reasons as claim 1.

Claim 15

Applicants note that the Office action rejects claims 1-15 in view of the combination of Leifheit/Leifheit et al./Hamilton et al. with Aneas, and then rejects claims 15-23 as being obvious in view of the combination of Leifheit/Leifheit et al./Hamilton et al. with U.S. Patent No. 5,738,831 (Bethel).

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It is believed that the rejection of claims 1-15 was intended to be limited to claims 1-14. No discussion of claim 15 or the subject matter thereof was provided on page 3 of the Office action in relation to the rejection of claims 1-15.

Claim 15 is directed to apparatus for producing chlorine dioxide gas, wherein the apparatus comprises a container defining an interior chamber, a first reaction component comprising a chlorite source and a second reaction component comprising at least one of an oxidizing agent and an acid releasing agent. The first and second reaction components are disposed within the interior chamber of the container and separated by at least one rupturable membrane whereby upon rupturing of the at least one membrane the first and second reaction components contact each other to form a reaction in which chlorine dioxide gas is produced within the interior chamber of the container. The container is constructed of a substantially liquid and gas impermeable material and has apertures formed therein in communication with the interior chamber of the container to permit exhaustion of chlorine dioxide gas from the interior chamber. The apparatus further comprises a gas permeable and substantially liquid impermeable substrate secured to the container over the apertures.

Claim 15 is submitted to be non-obvious in view of and patentable over the references of record, and in particular Leifheit, Leifheit et al. and Hamilton et al. in combination with Bethel, in that whether considered alone or in combination the references fail to disclose or suggest apparatus for producing chlorine dioxide gas wherein the apparatus comprises a container having a rupturable membrane separating first and second reaction components and constructed of a substantially liquid and gas impermeable material having apertures formed

therein in communication with the interior chamber of the container to permit exhaustion of chlorine dioxide gas from the interior chamber, wherein a gas permeable and substantially liquid impermeable substrate is secured to the container over the apertures.

Bethel disclose a bed linen deodorizer that disperses aromatic fragrance. In particular, the deodorizer (10) comprises (with reference to Figs. 3 and 4 as relied on by the Office) a base (14) having a plurality of side vents (32, 34, 36, 38, 30, 42, 44, 46) disposed about the periphery of the base between the outer edge (24) and the inner edge (26) of the base (see also Fig. 2). A pad (18) is seated in the base and is provided with a frangrance to be emitted by the deodorizer. As is clear from Fig. 4 of Bethel the pad (18) is sized to fit within the inner edge (26) of the base (14) and therefore does not cover any of the side vents of the base. A porous (e.g., spongy) material seats over the pad and allows the fragrance to be transmitted from the pad through the cover to provide the desired aromatic effet.

It is unclear from the Office action what components of Bethel the Office is characterizing as the liquid and gas impermeable container, the apertures therein, and the liquid impermeable but gas impermeable substrate that covers the apertures as recited in claim 15. As best understood, the Office equates the base (14) of Bethel with the recited container and equates the side vents of the base with the recited apertures in the container. However, it is clear that the side vents are uncovered by either the pad (18) or the cover (20). Rather, both the pad (18) and cover (20) are smaller than or equal to the inner edge (26) and therefore cannot cover the side vents.

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Moreover, neither the pad (18) nor the cover (20) is disclosed as being both liquid impermeable and gas permeable. Bethel teaches that the pad (18) is a fabric, such as cotton, and is therefore not liquid impermeable. The cover (20) is disclosed by Bethel as being a spongy, porous material. While Bethel teaches that the cover (20) is gas permeable, nowhere does Bethel teach that the spongy, porous material from which the cover is made is liquid impermeable. Nor is there any evidence on which the Office can deem the cover (20) to be inherently liquid impermeable. Indeed, sponges are typically liquid permeable. Thus, even if the side vents could be considered as being covered by the pad and/or cover (and applicants submit that they cannot), neither the pad nor the cover is a liquid impermeable substrate as recited in claim 1.

Accordingly, Bethel fail to disclose or otherwise even suggest a container constructed of a liquid and gas impermeable material and having apertures therein, and a liquid impermeable but gas permeable substrate covering the apertures.

Because Leifheit, Leifheit et al. and Hamilton et al. also each fail to disclose or suggest such features, a combination of these references with Bethel must also fail to disclose or suggest these features.

For the above reasons claim 15 is submitted to be nonobvious in view of and patentable over the references of record.

Claims 16-23 depend directly or indirectly from claim 15 and are submitted to be patentable over the references of record for the same reasons as claim 15.

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Discussion of New Claims Claim 24

New claim 24 corresponds generally to original claim 5 rewritten in independent form. In particular, the claim is directed to a chlorine dioxide gas generating kit comprising:

- a chlorine dioxide gas generating apparatus comprising:
- a container having a flexible outer wall defining an interior chamber of the container;
- a first reaction component and a second reaction component disposed within the interior chamber of the container; and
- at least one rupturable membrane disposed within the interior chamber of the container and separating the first and second reaction components, the at least one rupturable membrane being rupturable upon at least one of bending, compression, tension or puncture of the flexible outer wall of the container to permit contact between the first and second reaction components to thereby form a reaction in which chlorine dioxide gas is produced within the container;

the container being adapted for exhausting the chlorine dioxide gas therefrom; and

a substantially rigid receptacle defining an internal cavity sized and shaped for receiving at least a portion of the container of the chlorine dioxide gas generating apparatus so as to inhibit flexing and bending of the container to thereby inhibit unintended rupturing of said at least one rupturable membrane of the apparatus, the apparatus being removable from the receptacle for activating the apparatus to generate chlorine dioxide gas, said receptacle comprising a tubular sheath constructed of a substantially rigid material and having a central bore, at least a portion of the chlorine dioxide gas generating apparatus being slidably receivable in the central

bore of the sheath, the apparatus container being sized relative to the central bore of the sheath such that at least a portion of the apparatus container frictionally engages the sheath upon insertion of said at least a portion of the container in the central bore of said sheath to frictionally hold the apparatus within the receptacle.

As discussed at paragraph [0064] of the present application, in one exemplary embodiment the outer diameter of the central bore 907 of a sheath 905 is sized for frictional engagement with the gas generating apparatus container 927 upon insertion of the container therein whereby friction between the sheath 905 and the container inhibits unintended removal of the apparatus 921 from the sheath.

New claim 24 is submitted to be non-obvious in view of and patentable over the references of record, and in particular the combination of Leifheit, Leifheit et al. and Hamilton et al. with Aneas, in that whether considered alone or in combination the references fail to disclose or suggest the gas generating apparatus being frictionally held within a sheath.

In particular, Aneas disclose a removable sleeve (18) made of a more rigid material than the tubular body (4) to prevent inadvertent activation by the user. However, there is no disclosure or teaching found anywhere in Aneas that the sleeve (18) is sized for frictional engagement with the body (4) to frictionally hold the body within the sleeve. Moreover, there is no disclosure found in Aneas from which it can be said that the sleeve is inherently, i.e., necessarily, sized for frictional engagement with the tubular body. Accordingly, Aneas fail to disclose or suggest a sheath sized to frictionally engage the gas generating apparatus container to thereby frictionally hold the apparatus within the sheath.

suggest this feature.

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Because Leifheit, Leifheit et al. and Hamilton et al. each fail to disclose or suggest such a feature, a combination of these references with Aneas must also fail to disclose or

For these reasons, new claim 24 is submitted to be non-obvious in view of and patentable over the references of record.

CONCLUSION

For all of the foregoing reasons, favorable consideration and allowance of claims 1-10 and 15-24 as now presented is respectfully requested.

Respectfully submitted,

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